

Appln. No. 10/601,607
Atty. Dkt. No. 054707-1225

Reply to Office action dated September 7, 2004

Ex parte Fressola, 27 USPQ2d 1608 (BPAI 1993), the PTO noted that the claims must stand alone and, as such, incorporation by reference to the specification is permitted only in exceptional circumstances. *See* Office action, ¶ 2. The PTO recommended that the names or structures of each compound be explicitly incorporated into the claims. *See* Office action, ¶ 2.

Applicants traverse this rejection as claims 75 and 77 are clearly amenable to construction by those skilled in the art. *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001). A claim is sufficiently definite to satisfy the statutory requirement of 35 U.S.C. § 112, second paragraph, if one of ordinary skill in the art would understand the bounds of the claim when read in light of the specification. *See Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). In discussing this standard, the Federal Circuit stated that 35 U.S.C. § 112, second paragraph, requires simply "that the claims be amenable to construction." *See Exxon Research & Eng'g Co.*, 265 F.3d at 1375, 60 USPQ2d at 1276.

Claims 75 and 77 recite specific compounds which are clearly described in the pending application. Claim 75 recites "compounds 1-9, 21-25, 30-38, 42-57, 59, 66-97, A, B, C, D, and E." Likewise, claim 77 recites "compounds 4 and 76-94." Each of these compounds is described in detail from page 27, line 23 to page 35, line 20, of the application. As such, those skilled in the art would understand the bounds of the claim when read in light of the specification. *See Miles Labs., Inc.*, 997 F.2d at 875, 27 USPQ2d at 1126.

Moreover, the PTO regularly permits claims which reference the specification of patent applications. *See, e.g.*, 37 C.F.R. § 1.821(d). For example, Rule 1.821(d) states that

[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" . . . reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

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37 C.F.R. § 1.821(d).¹ In particular, Applicants note that this requirement is not tied to the size or nature of the sequences, i.e. it is unmoored from the requirements of necessity. *See id.*

Applicants find it unclear, therefore, why incorporation by reference is required in some contexts by the PTO while being forbidden in others. Such a result is arbitrary, capricious and contrary to the provisions of the Administrative Procedures Act. *See, e.g., Dickinson v. Zurko*, 142 F.3d 1447, 1449, 46 USPQ2d 1691, 1693 (Fed. Cir. 1998) (holding the PTO must adhere to the standards set forth in the Administrative Procedure Act).

Accordingly, Applications request withdrawal of this ground of rejection.

III. Provisional Rejection Under 35 U.S.C. § 102(e)

Claims 72-74, 75 in part, 76-77 and 80 were provisionally rejected under 35 U.S.C. § 102(e) as being anticipated by Magal, U.S. Application No. 09/159,105, which is the national stage prosecution of WO 99/14998. *See* Office Action, ¶ 3. Applicants traverse this ground of rejection.

Initially, Applicants note that WO 99/14998 is not a proper 35 U.S.C. § 102(e) reference. WO 99/14998 was filed September 24, 1998. As stated in MPEP § 706.02(f)(1).I.(C)(3), an international application with a filing date prior to November 20, 2000, can never be applied under 35 U.S.C. § 102(e). *See also* MPEP § 1857.01.

Applicants direct the PTO's attention to U.S. Patent Publication No. 2004/0186098 (available on the PTO IFW for consideration). However, in view of the remarks below, Applicants believe the PTO will not sustain this ground of rejection or assert a new ground of rejection.

¹ The PTO's promulgation of Rule 1.821 suggests that this ground of rejection is not based upon a statutory prohibition. *See* 5 U.S.C. § 706(2)(A) (2000) (providing rules which are arbitrary, capricious, or otherwise contrary to law, are to be held unlawful and set aside) (emphasis added).

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IV. Rejection Under 35 U.S.C. § 102(f)

Claims 72-74, 75 in part, 76-77 and 80 were rejected under 35 U.S.C. § 102(f) as being anticipated by compounds disclosed on pages 218-220 and compositions disclosed on pages 24-27 of WO 99/14998. *See* Office action, ¶ 4. The PTO noted that

the WO 99/14998 patent disclosed compositions and identical compounds with "different" inventorship and "different" assignee. The evidence raised the issue that applicants are not the first to conceive and reduce to practice the inventions since "another" was in possession of all the claimed species of compounds . . . and reduced it to practice.

See Office action, ¶ 4 (emphasis in original). Applicants respectfully traverse this rejection.

Applicants were in possession of claimed invention prior to the disclosure of WO 99/14998. Applicants first disclosed the claimed compounds and compositions in U.S. Provisional Application No. 60/087,842 (available on the PTO IFW for consideration), filed June 3, 1998, at page 30, line 12 to page 35, line 16.

Subsequently, Applicants consistently disclosed these compounds and compositions in applications relating back to this provisional application. Applicants disclosed these compounds and compositions at page 27, line 23 to page 34, line 4, of U.S. Patent Application No. 09/204,236 (available on the PTO IFW for consideration), filed December 3, 1998. Applicants then disclosed these compounds and compositions at page 27, line 23 to page 34, line 4, of U.S. Patent Application No. 09/791,660 (available on the PTO IFW for consideration), filed February 26, 2001.

This consistent, complete disclosure shows Applicants were in possession of the compounds and compositions from at least June 3, 1998.

In contrast, the publicly available priority documents of WO 99/14998 do not evidence invention prior to June 3, 1998. In fact, neither U.S. Provisional Application No. 60/059,905 (available on the PTO IFW for consideration) nor U.S. Provisional Application No. 60/059,963

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(available on the PTO IFW for consideration) disclose invention of the presently claimed compounds or compositions.

Moreover, it appears that the named inventor of WO 99/14998, Magal, derived the her compounds from other investigators. For example, Magal disclosed compounds reported by others on page 133 (Compound 167), page 134 (Compound 168), page 135 (Compounds 169-171 and 172-175), page 136 (Compound 176), pages 137-139 (Compounds 177-187), pages 139-141 (Compounds 188-196), page 141 (Compound 197), page 142 (Compounds 198-200), pages 142-145 (Compounds 201-221), page 145-147 (Compounds 222-234), page 147-152 (Compounds 235-249), page 152 (Compound 250), pages 152-162 (Compounds 251-254), and pages 165-167 (Compounds of Formula LVI). Additionally, it is apparent that Magal was intimately familiar with Applicants' own compounds and research. *See, e.g.*, WO 99/14998, pages 3-10 (citing Applicants' research publications and patents).

Most significantly, Magal admitted using the Applicants' compounds. For example, U.S. Provisional Application No. 60/059,963 teaches that the compounds used for treating hearing loss were derived from the Applicants' prior patents and publications, i.e. Steiner et al., *Proc. Natl. Acad. Sci USA* 94:2019-2024 (1997) and U.S. Patent No. 5,614,547. *See* Page 10, line 25 to page 12, line 6. Inexplicably, Magal *omitted* this fact from each subsequent application. As such, this evidence strongly supports a finding that Magal derived the compounds from the Applicants.

In view of the above, this ground of rejection should be withdrawn.

V. Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

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The PTO is invited to contact the undersigned attorney by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date December 7, 2004

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By 

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 CFR § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.